



Express Mail No.: EV 335 858 849 US

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of: Young et al.

Confirmation No.: 7010

Application No.: 09/724,531

Group Art Unit: 1648

Filed: November 28, 2000

Examiner: Chen, Stacy S.

For: METHODS OF ADMINISTERING/  
DOSING ANTI-RSV ANTIBODIES  
FOR PROPHYLAXIS AND  
TREATMENT

Attorney Docket No.: 10271-021

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §1.56 AND §1.97**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 and § 1.97 to inform the Patent Office of all references coming to the attention of each individual associated with the filing or prosecution of the subject application, which are or may be material to the patentability of any claim of the application, Attorneys for Applicants hereby invite the Examiner's attention to the references **DL-FP** listed on the attached revised form PTO 1449 entitled "List of References Cited by Applicant." Copies of references **DL-FP** are submitted herewith.

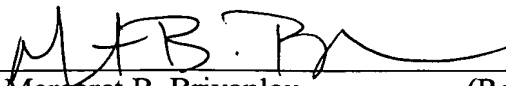
Identification of the listed references is not meant to be construed as an admission of Applicants or Attorneys for Applicants that such references are available as "prior art" against the subject application. Consequently, Applicants respectfully decline to use form PTO-1449, since this form identifies all of the references cited therein as "Prior Art." As an alternative, Applicants submit herewith a "revised form PTO 1449" entitled "List of References Cited" instead of "List of Prior Art Cited."

Applicants respectfully request that the Examiner review the foregoing references and that the references be made of record in the file history of the application.

Pursuant to 37 C.F.R. § 1.97(b), Applicants estimate that no fee is due in connection with the filing of this Information Disclosure Statement. However, should the Patent Office determine otherwise, please charge the necessary fee to Jones Day Deposit Account No. 503013. A duplicate of this sheet is enclosed for accounting purposes.

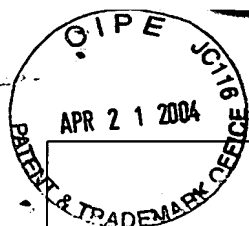
Respectfully submitted,

Date April 21, 2004

  
Margaret B. Brivanlou 40,922  
(Reg. No.)

**Jones Day**  
1155 Avenue of the Americas  
New York, New York 10036-2711  
(212) 790-9090

Enclosures


**LIST OF REFERENCES CITED BY APPLICANT**

(Use several sheets if necessary)

ATTY DOCKET NO.

10271-021-999

APPLICATION NO

09/724,531

APPLICANT

Young et al.

FILING DATE

November 28, 2000

GROUP

1641

**U.S. PATENT DOCUMENTS**

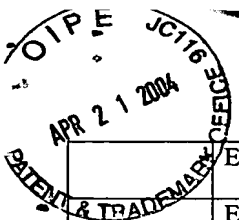
| *EXAMINER<br>INITIAL |    | DOCUMENT NUMBER | DATE     | NAME          | CLASS | SUBCLASS | FILING DATE<br>IF<br>APPROPRIATE |
|----------------------|----|-----------------|----------|---------------|-------|----------|----------------------------------|
|                      | DU | 6,537,809       | 3/25/03  | Brams         |       |          |                                  |
|                      | DV | 6,096,551       | 8/1/00   | Barbas et al. |       |          |                                  |
|                      | DW | 5,693,762       | 12/2/97  | Queen et al.  |       |          |                                  |
|                      | DX | 5,585,089       | 12/17/96 | Queen et al.  |       |          |                                  |
|                      | DL | 5,939,068       | 8/17/99  | Brams et al.  |       |          |                                  |

**FOREIGN PATENT DOCUMENTS**

|  |    | DOCUMENT NUMBER | DATE    | COUNTRY | CLASS | SUBCLASS | TRANSLATION |
|--|----|-----------------|---------|---------|-------|----------|-------------|
|  |    |                 |         |         |       |          | YES NO      |
|  | DY | WO 00/29584     | 5/25/00 | PCT     |       |          |             |
|  | DM | WO 96/05229     | 2/22/96 | PCT     |       |          |             |

**OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)**

|  |    |  |
|--|----|--|
|  | DZ | Anderson et al., 1985, "Microneutralization test for respiratory syncytial virus based on an enzyme immunoassay," J. Clin. Microbiol. 22:1050-1052   |
|  | EA | Boulianne et al., 1984, "Production of functional chimaeric mouse/human antibody," Nature 312(5995):643-646  |
|  | EB | Carson et al., 1986, "Human lymphocyte hybridomas and monoclonal antibodies," Adv. Immunol. 38:275-311   |
|  | EC | Conrad et al., 1987, "Aerosolized ribavirin treatment of respiratory syncytial virus infection in infants hospitalized during an epidemic," Pediatr. Infect. Dis. J. 6(2):152-158  |
|  | ED | Cruse et al., 1995, Illustrated Dictionary of Immunology, Boca Raton: CRC Press, pp. 18-19   |
|  | EE | Dorland's Illustrated Medical Dictionary, 1994, 28 <sup>th</sup> ed., Philadelphia: WB Saunders p. 874   |
|  | EF | Duenas et al., 1996, "In vitro immunization of naive human B cells yields high affinity immunoglobulin G antibodies as illustrated by phage display," Immunology 89:1-7  |
|  | EG | Duenas et al., 1996, "Selection of phage displayed antibodies based on kinetic constants," Molecular Immunol. 33(3):279-285  |
|  | EH | Everitt et al., 1996, "The pharmacokinetics, antigenicity, and fusion-inhibition activity of RSHZ19, a humanized monoclonal antibody to respiratory syncytial virus, in healthy volunteers," J. Infect. Dis. 174:463-469         |
|  | EI | Foote et al., 1995, "Kinetic and affinity limits on antibodies produced during immune response," Proc. Nat'l Acad. Science USA 92:1254-1256  |
|  | EJ | Foote et al., 1991, "Kinetic maturation of an immune response," Nature 352:530-532   |
|  | EK | Glaser et al., 1992, "Antibody engineering by codon-based mutagenesis in a filamentous phage vector system," J. Immunol. 149:3903-3913   |
|  | EL | Greenspan et al., 1999, "Defining epitopes: It's not as easy as it seems," Nature Biotechnology 17:936-937   |
|  | EM | Groves et al., 1987, "Production of an ovine monoclonal antibody to testosterone by an interspecies fusion," Hybridoma 6(1):71-76  |
|  | EN | Hall et al., 1985, "Ribavirin treatment of respiratory syncytial viral infection in infants with underlying cardiopulmonary disease," JAMA 254(21):3047-3051   |
|  | EO | Hall et al., 1983, "Aerosolized ribavirin treatment of infants with respiratory syncytial viral infection. A randomized double-blind study," N. Engl. J. Med. 308(24):1443-1447  |
|  | EP | Hall et al., 1975, "Nosocomial respiratory syncytial virus infections," N. Engl. J. Med. 293(26):1343-1346   |
|  | EQ | Haynes et al., 2002, "Neutralizing anti-F glycoprotein and anti-substance P antibody treatment effectively reduces infection and inflammation associated with respiratory syncytial virus infection," J. Virol. 76(14):6873-6881 |



|    |  |
|----|--|
| ER | Johnson et al., 1999, "A direct comparison of the activities of two humanized respiratory syncytial virus monoclonal antibodies: MEDI-493 and RSHZ19," J. Infect. Dis. 180(1):35-40  |
| ES | Karlsson et al., 1997, "Experimental design for kinetic analysis of protein-protein interactions with surface plasmon resonance biosensors," J Immunol. Meth. 200:121-133  |
| ET | Knappik et al., 2000, "Fully synthetic human combinatorial antibody libraries (HuCAL) based on modular consensus frameworks and CDRs randomized with trinucleotides," J. Mol. Biol. 296:57-86  |
| EU | Liu et al., 1987, "Expression of mouse::human immunoglobulin heavy-chain cDNA in lymphoid cells," Gene 54(1):33-40   |
| EV | LoBuglio et al., 1989, "Mouse/human chimeric monoclonal antibody in man: kinetics and immune response," Proc. Natl. Acad. Sci. USA 86(11):4220-4224  |
| EW | Morrison et al., 1985, "Transfectomas provide novel chimeric antibodies," Science 229(4719):1202-1207  |
| EX | Morrison et al., 1984, "Chimeric human antibody molecules: mouse antigen-binding domains with human constant region domains," Proc. Natl. Acad. Sci. USA 81(21):6851-6855  |
| EY | Myszka et al., 1999, "Survey of the 1998 optical biosensor literature," J. Mol. Recog. 12:390-408  |
| EZ | Newman et al., 1992, "'Primitization' of recombinant antibodies for immunotherapy of human diseases: A Macaque/Hunab chimeric antibody against human CD4," Biotechnol. 10:1455-1460  |
| FA | Prince et al., 1996, "Treatment of parainfluenza virus type 3 bronchiolitis and pneumonia in a cotton rat model using topical antibody and glucocorticosteroid," J. Infect. Dis. 173:598-608   |
| FB | Raman et al., 1992, "Diffusion-limited rates for monoclonal antibody binding to cytochrome," Biochem. 31:10370-10379   |
| FC | Roost et al., 1995, "Early high-affinity neutralizing anti-viral IgG responses without further overall improvements of affinity," PNAS USA 92:1257-1261  |
| FD | Rosok et al., 1995, "A combinatorial library strategy for the rapid humanization of anticarcinoma BR 96 Fab," JBC 271(27):22611-22618  |
| FE | Rudikoff et al., 1982, "Single amino acid substitution altering antigen-binding specificity," Proc. Natl. Acad. Sci. USA 79(6):1979-1983   |
| FF | Sahagan et al., 1986, "A genetically engineered murine/human chimeric antibody retains specificity for human tumor-associated antigen," J. Immunol. 137(3):1066-1074   |
| FG | Schier et al., 1996, "Isolation of picomolar affinity anti-c-erbB-2 single-chain Fv by molecular evolution of the complementarity determining regions in the center of the antibody binding site," J. Mol. Biol. 263(4):551-567  |
| FH | Steplewski et al., 1988, "Biological activity of human-mouse IgG1, IgG2, IgG3, and IgG4 chimeric monoclonal antibodies with antitumor specificity," Proc. Natl. Acad. Sci. USA 85(13):4852-4856  |
| FI | Sun et al., 1987, "Chimeric antibody with human constant regions and mouse variable regions directed against carcinoma-associated antigen 17-1A," Proc. Natl. Acad. Sci. USA 84(1):214-218   |
| FJ | Takeda et al., 1985, "Construction of chimaeric processed immunoglobulin genes containing mouse variable and human constant region sequences," Nature 314(6010):452-454  |
| FK | Talwar et al., 1976, "Isoimmunization against human chorionic gonadotropin with conjugates of processed beta-subunit of the hormone and tetanus toxoid," Proc. Natl. Acad. Sci. USA 73(1):218-222  |
| FL | van Wyke et al., 1985, "Antigenic variation in the hemagglutinin-neuraminidase protein of human parainfluenza type 3 virus," Virology 143(2):569-582   |
| FM | Wald et al., 1988, "In re ribavirin: a case of premature adjudication?" J. Pediatr. 112(1):154-158   |
| FN | Wright et al., 1982, "Administration of a highly attenuated, live respiratory syncytial virus vaccine to adults and children," Infect. Immun. 37(1):397-400  |
| FO | Wu et al., 1998, "Stepwise in vitro affinity maturation of Vitaxin, an avb-specific humanized mAb," PNAS 95:6037-6042  |
| FP | Geneseq Database, Accession no: AAW70933, entry date Oct. 1998 from patent no FR2758331-A1 of Bourgeois et al.   |
| DN | Hacking et al., 2002, "Respiratory syncytial virus - viral biology and the host response," J. Infection 45:18-24   |
| DO | Heard et al., 1999, "Two neutralizing human RSV antibodies: cloning, expression, and characterization," Mol. Med. 5:35-45  |
| DP | Landry et al., "Evaluation of reconstituted lyophilized palivizumab given intravenously at 15 and 30 mg/kg," Poster Session, Infect. Dis. 166A: 969  |
| DQ | Saez-Llorens et al., 1997, "Phase I/II open label multi dose escalation trial of a humanized respiratory syncytial virus (RSV) monoclonal antibody (Medi-493) administered intramuscularly (IM) in high risk children," Abstracts in Non-HIV virology, Intersci. Conf. Antimicrob. Agents Chemother. Toronto |
| DR | Subramanian et al., 1997, "Randomized double blind placebo controlled dose escalation trial of a humanized respiratory syncytial virus monoclonal antibody in high risk infants," Poster session infect. dis. 130A:768   |
| DS | Sorbera et al., 1998, "Palivizumab," Drugs of the Future 23:970-976  |
| DT | Sorbera et al., 1998, "Palivizumab," Drug Data Report 20:702-703   |

**EXAMINER**

**DATE CONSIDERED**

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.